UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

| ANNA TONER | |
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| Plaintiff, | Case No. |
| NEW ENGLAND COMPOUNDING PHARMACY, INC. d/b/a NEW ENGLAND COMPOUNDING CENTER, | |
| Defendant. | / |
| JOHN T. ALEXANDER (P43789) Alexander & Angelas, P.C. Attorneys for Plaintiff 30200 Telegraph Road, Suite 400 Bingham Farms, Michigan 48025-4506 (248) 290-5600 john@alexanderandangelas.com | |

PLAINTIFF'S FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

NOW COMES the above-named Plaintiff, Anna Toner, by and through her attorneys, Law Offices of Alexander & Angelas, P.C., and complaining against the above-named Defendant and states as follows:

GENERAL ALLEGATIONS

 That Plaintiff's domicile is located in the County of Livingston, State of Michigan.

- 2. That Defendant New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, is incorporated under the laws of the State of Massachusetts, and its principal place of business is located in the State of Massachusetts.
 - 3. That this cause of action arose in the State of Michigan.
 - 4. That the amount in controversy is in excess of \$75,000.00.
 - 5. That this Honorable Court has diversity jurisdiction pursuant to 28 USC §1332.
- 6. That Defendant is a compounding pharmacy and in the ordinary course of their business, made large batches of steroids for use in patient injections.
 - 7. That said steroid batches contained methylprednisolone acetate (MA).
- 8. That the Defendant negligently allowed fungus and other contaminates into the MA during the compounding process.
- 9. That when the MA was placed into bottles, there was visible particulate black matter.
- 10. That these contaminated vials of MA were shipped to many states for the purpose of patient injections.
- 11. That Michigan Pain Clinic located in Brighton Michigan received some of these contaminated vials.
- 12. That Plaintiff, Anna Toner, received three steroid injections of the contaminated vials on June 27, 2012, August 22, 2012, and September 20, 2012.
- 13. That as a proximate result of being injected by the contaminated steroid, Plaintiff suffered numerous injuries including fungal meningitis, effecting her brain, organs, and delaying a back surgery.

COUNT I

(NEGLIGENT PRODUCTION)

- 14. Plaintiff realleges and incorporates by reference herein paragraphs 1 through 13 above as though more fully set forth herein.
- 15. That Defendant is engaged in the business of manufacturing and/or compounding medications including MA.
- 16. That Defendant manufactured and/or compounding several batches of MA that were contaminated with fungus, mold and other contaminates.
- 17. That Defendant is not an accredited institution of the Pharmacy Compounding Accreditation Board.
- 18. That these contaminated batches of MA was distributed to several states including Michigan and specifically the Brighton Pain Clinic located in Brighton, Michigan.
- 19. That as a direct and proximate result of the contaminated MA, Plaintiff, Anna Toner, suffered serious injuries including fungal meningitis and related complications to her brain, body, and organs.
- 20. That according to by State and Federal health officials thus far, 304 people were sickened and 23 have died.
- 21. That according to State and Federal health investigations thus far, the MA batches were contaminated by a variety of reasons including the Defendant's failing to keep manufacturing equipment sanitary, operated a leaky boiler room near the "clean room" where drugs were packaged, dirty floor mats that pharmacy staff used to wipe their shoes before entering the lab that were visibly soiled, machines that protect staff from inhaling substances during manufacturing were not thoroughly cleaned and powder was visible on the hoods and

further that the Defendant was found to have a systematic failure to sterilize products that required a minimum 20 minutes sterilization necessary to ensure product sterility. Nor was any testing done by the Defendant to make sure the equipment was clean and functioning properly.

- 22. That the Defendant had actual knowledge that the product MA was defective and that there was substantial likelihood that the defect would cause the injury that is the basis of this action, and the Defendant willfully disregarded that knowledge in the manufacture and distribution of the product.
- 23. That it was foreseeable that the contaminated MA would cause injury to patients, and specifically Plaintiff;
- 24. That it was foreseeable or reasonably discoverable to Defendant, at the time the subject product was designed, manufactured, compounded, assembled, inspected, monitored, distributed, and/or sold that a meningitis type injury would occur to an individual similarly situated to the Plaintiff due to the contaminated medication.
- 25. That Defendant, as designer, manufacturer, compounder, assembler, inspector, monitor, maintainer, distributor, and/or vendor of the aforesaid product, owed the general public and Plaintiff, in particular, a duty of introducing only safe products into the stream of commerce; and conversely not to allow unsafe products to be placed into the stream of commerce.
 - 26. That more specifically, it was the duty of Defendant to use reasonable care in the:
 - A. design, manufacture, assembly, compounding, inspecting, and monitoring the subject product so it would be reasonably safe for its intended use, foreseeable misuses, and to eliminate unreasonable and foreseeable risk of harm;
- 27. That Defendant sold the subject product in a defective condition, as aforementioned, which was unreasonably dangerous to the users of said product and in particular to the Plaintiff.

28. That Plaintiff, as a recipient of the subject product, was in the class of persons within the foreseeable scope at risk of injury.

COUNT II

(BREACH OF EXPRESS/IMPLIED WARRANTY)

- 29. Plaintiff realleges and incorporates by reference herein paragraphs 1 through 28 above as though more fully set forth herein.
- 30. That Defendant, as designer, manufacturer, compounder, assembler, inspector, monitor, distributor and/or seller of the subject product expressly and impliedly warranted that its product was of merchantable quality and reasonably safe for the anticipated or reasonably foreseeable purposes, uses, and misuses.
- 31. That more specifically Defendant expressly and impliedly warranted that the design, manufacture, compound, assembly, inspection, distribution and/or sale of the subject product would not subject users and/or operators such as Plaintiff, to unreasonable risks of harm and/or injury.
- 32. That Defendant breached each and every one of the aforesaid warranties by failing to design, manufacture, compound, assemble, inspect, monitor, distribute and/or sell said product in merchantable quality and reasonably safe condition for the anticipated or reasonably foreseeable purposes, uses, and misuses.
- 33. That as a direct and proximate result of Defendant's aforementioned breach of warranties, Plaintiff suffered severe, painful and permanent injuries and economic damages as more fully stated supra.
- 34. That said product was not reasonably fit for its use at the time it left Defendant's control.
- 35. That as a direct and proximate result of Defendant's aforementioned breach of warranties, Plaintiff suffered injuries as more fully stated *infra*

COUNT III

(DUTY TO WARN)

- 36. Plaintiff realleges and incorporates by reference herein paragraphs 1 through 35 above as though more fully set forth herein.
- 37. That it was foreseeable or reasonably discoverable to the Defendant at the time the subject product was designed, manufactured, compounded, assembled, inspected, monitored, distributed, and/or sold a meningitis type injury would occur to an individual similarly situated to the Plaintiff, due to the product being contaminated.
- 38. That Defendant, as designer, manufacturer, compounder, assembler, inspector, monitor, maintainer, distributor, and/or vendor of the aforesaid product, owed that general public an plaintiff, in particular, a duty of introducing only safe products into the stream of commerce; and conversely not to allow unsafe products to be placed into the stream of commerce.
 - a. design, manufacture, compound, assemble, compound, inspect, and monitor the subject product, so it would be reasonably safe for its intended use, foreseeable misuses, and to eliminate unreasonable and foreseeable risk of harm:
 - b. warn those who purchased the subject product and those patients who received injections of the dangers attendant to use of said product;
 - c. place clear and conspicuous warnings, on the subject product, to warn against and prevent using said product;
 - d. recall said product to prevent its use on patients. That Defendant breached each and every one of the aforementioned duties as above stated by negligently failing to perform same
- 39. That Defendant sold the subject product in a defective condition, as aforementioned, which was unreasonably dangerous to the users and bystanders of said product and in particular, the Plaintiff.
- 40. That Plaintiff, as a recipient of the subject product, was in the class of persons within the foreseeable scope at risk of injury.

COUNT IV

(VIOLATION OF MICHIGAN CONSUMER PROTECTION ACT)

- 41. Plaintiff realleges and incorporates by reference herein paragraphs 1 through 40 above as though more fully set forth herein.
- 42. That pursuant to MCLA 445.903 Defendants have a duty not to be unfair, unconscionable, or deceptive in their methods, acts, or practices in its conduct of trade or commerce.
- 43. That by placing into the stream of commerce contaminated vials of MA, the Defendant has violated the Michigan Consumer Protection Act in the following particulars:
 - a. Causing a probability of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services;
 - b. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has sponsorship, approval, status, affiliation, or connection that he or she does not have.
 - c. Representing that goods are new if they are deteriorated, altered, reconditioned, used, or secondhand.
 - d. Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.
 - e. Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer.
 - f. Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is.
- 44. That as a proximate result of the violation of the Michigan Consumer Protection Act, Plaintiff suffered injuries as more fully set forth herein.

COUNT V

(EXEMPLARY DAMAGES)

- 45. Plaintiff realleges and incorporates by reference herein paragraphs 1 through 44 above as though more fully set forth herein.
- 46. That Plaintiff is requesting exemplary damages as compensation of injuries attributable solely to Defendant's bad faith or ill will.

COUNT VI

(DAMAGES)

- 47. Plaintiff realleges and incorporates by reference herein paragraphs 1 through 46 above as though more fully set forth herein.
- 48. That as a proximate result of each of the above-mentioned violations of the Defendant, the injured Plaintiff suffered the following damages:
 - a. Pain and suffering;
 - b. Disability;
 - c. Aggravation of pre-existing condition;
 - e. Mental anguish;
 - f. Denial of social pleasures and enjoyment;
 - g. Embarrassment, humiliation and mortification;
 - h. Fright and shock;
 - i. Miscellaneous expenses; and,
 - j. Interest.

WHEREFORE, Plaintiff respectfully request judgment in her favor, and against Defendant, in an amount in excess of \$75,000.00 excluding, interest, costs, attorney fees, and exemplary damages.

Law Offices of ALEXANDER & ANGELAS, P.C.

By: /s/ John T. Alexander JOHN T. ALEXANDER (P43789) Attorney for Plaintiff 30200 Telegraph Road, Suite 400 Bingham Farms, MI 48025 (248) 290-5600

DATED: December 21, 2012